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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,247	07/01/2005	Mujun Zhao	SPT-0001	6598

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OSHA LIANG L.L.P.
TWO HOUSTON CENTER
909 FANNIN, SUITE 3500
HOUSTON, TX 77010

EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
10/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@oshaliang.com
buta@oshaliang.com

Office Action Summary	Application No.	Applicant(s)	
	10/541,247	ZHAO ET AL.	
	Examiner	Art Unit	
	AMY BOWMAN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/15/9*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7 and 17-21* is/are pending in the application.

4a) Of the above claim(s) *20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed 6/15/09 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 1/14/09 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6, 7, and 17-21 are pending in the instant application.

Claims 6, 7, and 17-19 are rejected under 35 USC 103(a) below. In view of the instant rejection, there is no unity of invention as there is no special technical feature linking the groups.

This application contains claims 20 and 21 that are drawn to an invention nonelected with traverse (election by original presentation) in the reply filed on 6/15/09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendments and/or arguments filed 6/15/09 have been fully considered but are not considered persuasive for the reasons explained below. A new ground of rejection is applied in view of the instant claim amendments as set forth below.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted that a translation of said papers has not been made of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 7, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over NCI-CGAP EST sequence (http://www.ncbi.nlm.nih.gov/ncicgap, Accession AI241478, mRNA linear EST 01-DEC-1998, (see sequence results in SCORE, search labeled "20081218_105428_us-10-541-247-1.sl.rst", result #12)).

The instant claims are directed to a pharmaceutical composition comprising an antagonist of an HLRTM4 gene or gene transcript, wherein the hLRTM4 gene has a sequence of SEQ ID NO: 1, wherein the antagonist is a polynucleotide having a fragment of at least 15, 30, or 50 bases that hybridize to the hLRTM4 gene or the hLRTM4 gene transcript, and a pharmaceutically acceptable vehicle, diluent, or carrier.

The sequence of the prior art is 507 nucleotides and length and is 100% complementary to nucleotides 228-625 of instant SEQ ID NO: 1 at nucleotides 42-439 of the EST sequence and is therefore complementary to at least 30, 50, or 100 bases of the instant target sequence.

Although the sequence is not disclosed as an antagonist of a hLRTM4 gene or gene transcript, the sequence meets each of the instantly recited structural limitations and therefore would necessarily be an antagonist of a hLRTM4 gene or gene transcript. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property.

The following EST sequence is disclosed as a homo sapiens EST wherein the cDNA was ligated to EcoR1 adapters, digested with Pac1, and cloned into the Pac1 and EcoR1 sites of the modified PT7T3.

The search result is as follows:

RESULT 12
AI241478/c
LOCUS AI241478 507 bp mRNA linear **EST 01-DEC-1998**

DEFINITION qh69b11.x1 Soares_fetal_liver_spleen_1NFLS_S1 Homo sapiens cDNA clone IMAGE:1849917 3' similar to SW:ILT4_HUMAN P48230 TETRASPAN MEMBRANE PROTEIN IL-TMP. ;, mRNA sequence.
ACCESSION AI241478
VERSION AI241478.1 GI:3836875
KEYWORDS EST.
SOURCE Homo sapiens (human)
ORGANISM Homo sapiens
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini; Catarrhini; Hominidae; Homo.
REFERENCE 1 (bases 1 to 507)
AUTHORS NCI-CGAP http://www.ncbi.nlm.nih.gov/ncicgap.
TITLE National Cancer Institute, Cancer Genome Anatomy Project (CGAP), Tumor Gene Index
JOURNAL Unpublished (1997)
COMMENT Contact: Robert Strausberg, Ph.D.
Email: cgapbs-r@mail.nih.gov
This clone is available royalty-free through LLNL ; contact the IMAGE Consortium (info@image.llnl.gov) for further information.
Insert Length: 570 Std Error: 0.00
Seq primer: -40UP from Gibco
High quality sequence stop: 361.
FEATURES Location/Qualifiers
source 1. .507
/organism="Homo sapiens"
/mol_type="mRNA"
/db_xref="taxon:9606"
/clone="IMAGE:1849917"
/sex="male"
/dev_stage="20 week-post conception fetus"
/lab_host="DH10B (ampicillin resistant)"
/clone_lib="Soares_fetal_liver_spleen_1NFLS_S1"
/note="Organ: Liver and Spleen; Vector: pT7T3D (Pharmacia) with a modified polylinker; Site_1: Pac I; Site_2: Eco RI; This is a subtracted version of the original Soares fetal liver spleen 1NFLS library. 1st strand cDNA was primed with a Pac I - oligo(dT) primer [5' AACTGGAAGAATTAATTAAAGATCTTTTTTTTTTTTTTTTTTT 3'],

double-stranded cDNA was ligated to Eco RI adaptors (Pharmacia), digested with Pac I and cloned into the Pac I and Eco RI sites of the modified pT7T3 vector. Library went through one round of normalization. Library constructed by Bento Soares and M.Fatima Bonaldo."

ORIGIN

Query Match 73.7%; Score 460.8; DB 1; Length 507;
Score over Length 90.9%;
Best Local Similarity 99.1%; Pred. No. 1.3e-123;
Matches 462; Conservative 0; Mismatches 4; Indels 0; Gaps 0;

```
Qy      160
TTCGGAGGAATATTAGGAAGCGGTGTCTTGATGATCTTCCCTGCGCTGGTGTTCTTGGGC 219
        |||| |||||||||| |||||||||||||||||||||| ||||||||||||||||||
Db      507
TTCGNAGGAATATTAGNAAGCGGTGTCTTGATGATCTTCCTTGCGCTGGTGTTCTTGGGC 448

Qy      220
CTGAAGAACAATGACTGCTGTGGGTGCTGCGGCAACGAGGGCTGTGGGAAGCGATTTGCG 279
        ||||||| ||||||||||||||||||||||||||||||||||||||||||||||||
Db      447
CTGAAGACCAATGACTGCTGTGGGTGCTGCGGCAACGAGGGCTGTGGGAAGCGATTTGCG 388

Qy      280 ATGTTCACCTCCACGATATTTGCTGTGGTTGGATTCTTGGGAGCTGGATACTCGTTTATC
339
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      387 ATGTTCACCTCCACGATATTTGCTGTGGTTGGATTCTTGGGAGCTGGATACTCGTTTATC
328

Qy      340
ATCTCAGCCATTTCAATCAACAAGGGTCCTAAATGCCTCATGGCCAATAGTACATGGGGC 399
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      327
ATCTCAGCCATTTCAATCAACAAGGGTCCTAAATGCCTCATGGCCAATAGTACATGGGGC 268

Qy      400
TACCCCTTCCACGACGGGGATTATCTCAATGATGAGGCCTTATGGAACAAGTGCCGAGAG 459
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      267
TACCCCTTCCACGACGGGGATTATCTCAATGATGAGGCCTTATGGAACAAGTGCCGAGAG 208

Qy      460
CCTCTCAATGTGGTTCCCTGGAATCTGACCCTCTTCTCCATCCTGCTGGTCGTAGGAGGA 519
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      207
CCTCTCAATGTGGTTCCCTGGAATCTGACCCTCTTCTCCATCCTGCTGGTCGTAGGAGGA 148

Qy      520
ATCCAGATGGTTCTCTGCGCCATCCAGGTGGTCAATGGCCTCCTGGGGACCCTCTGTGGG 579
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      147
ATCCAGATGGTTCTCTGCGCCATCCAGGTGGTCAATGGCCTCCTGGGGACCCTCTGTGGG 88
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Qy      580 GACTGCCAGTGTTGTGGCTGCTGTGGGGGAGATGGACCCGTTTAAA 625
            ||||||||||||||||||||||||||||||||||||||||||||||
Db       87 GACTGCCAGTGTTGTGGCTGCTGTGGGGGAGATGGACCCGTTTAAA 42
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Although the reference does not specifically teach that the polynucleotide is in a composition with a pharmaceutically acceptable vehicle, diluent, or carrier, the polynucleotide would have to be in a composition with a buffer, diluent, or water to perform the ligation, digestion, and cloning into the vector, as disclosed in the features of the above-cited sequence. One of skilled in the art would recognize that the polynucleotide is in a composition with a pharmaceutically acceptable vehicle, diluent, or carrier to practice these methods.

For these reasons, it would have been obvious to put the polynucleotide in a composition with a pharmaceutically acceptable vehicle, diluent. One would have been motivated to do so to practice the ligation, digestion, and cloning of the prior art, as well as for storage of the vector. One would have a reasonable expectation that formulation of a composition with the polynucleotide and a pharmaceutically acceptable vehicle, carrier, or diluent would aid in the stability and integrity of the polynucleotide or vector comprising the polynucleotide.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant argues that the sequence of AI241478 is complementary to the instant sequence at 397 contiguous bases, but is not a contiguous fragment of 30-100 bases.

Contrary to applicant's argument, the instant claim language "having" a contiguous fragment of 30-100 bases is open language and therefore the longer sequence of AI241478 has a contiguous fragment of 30-100 bases plus additional sequence, which anticipates the instant claims.

Furthermore, instant claim 18 is consistent with this interpretation given that the claim requires for the contiguous fragment to be at least 100 bases. Otherwise, the claim fails to further limit the base claim.

Amendment of claim 6 to recite "wherein the antagonist is a polynucleotide consisting of a contiguous fragment of 30-100 bases…", for example, would close the language and overcome this rejection.

New Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 7, and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Instant claim 1 requires for the antagonist to be of the hLRTM4 gene or gene transcript and to have a contiguous fragment of 30-100 bases that hybridize to the gene or gene transcript.

Upon a review of the specification, and particularly of the passages pointed to by applicant, the size limitations are disclosed in the context of a polynucleotide that hybridizes to the gene transcript, rather than to the gene itself.

Amendment to omit "hLRTM4 gene", thereby requiring the contiguous fragment to hybridize to the gene transcript, would obviate this rejection.

MPEP §2163.06 notes:

> If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

> Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

Should applicant disagree, applicants are encouraged to point out with particularity by page and line number where such support might exist for each claim limitation added in the amended claims filed on 6/15/09.

There is no support for this claim limitation in the claimed priority documents. Therefore, the effective filing date of the instant claims is considered, for purposes of prior art, to be 7/1/05, which is the filing date of the instant application.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMY BOWMAN
Primary Examiner
Art Unit 1635

/AMY BOWMAN/
Primary Examiner, Art Unit 1635